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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/657,703 | 09/09/2003 | Alice Marie Pebay | P08048US00/BAS | 6086 |
| 881 | 7590 | 07/07/2006 | EXAMINER GAMETT, DANIEL C | |
| STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314 | | | ART UNIT 1647 | |

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,703

Applicant(s)

PEBAY ET AL.

Examiner

Daniel C. Gamett, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 8-66, 69, 78, 80, 87-89, 94, and 96-109 is/are pending in the application.
- 4a) Of the above claim(s) 2, 17-40, 42-62, 64, 74-78, 80, 87-89, 94, and 96-108 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8-16, 41, 63, 65, 66, 69-73 and 109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 5, 8-66, 69, 78, 80, 87-89, 94, and 96-109 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/30/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments of 04/20/2006 have been entered in full. Claims 4, 6, 7, 67, 68, 79, 81-86, 90-93 and 95 are cancelled. Previously withdrawn claims 10-12 and 71-73, as amended, are drawn to elected subject matter and will be examined in this office action.
2. Claims 2, 17-40, 42-62, 64, 74-78, 80, 87-89, 94, and 96-108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1, 3, 8-16, 41, 63, 65, 66, 69-73, and 109 are under examination.
3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a Markush group of molecules. Said Markush group includes “a serum”. Serum is not a molecule.
6. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites “functional equivalents thereof inhibit differentiation of the stem cell.” It seems that words are missing from this limitation. For purposes of examination, it

will be assumed that the intent was that the claim should read "...thereof *capable of inhibiting*..." or "...thereof *that inhibit*..."

7. Rejection of claims 1, 3, 8, 9 14-16, 41, 63, 65, 66, 69, and 70, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and hereby extended to claims 10-13, 71-73, and 109. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's arguments filed 04/20/2006 have been fully considered but they are not persuasive.
8. Regarding claims 3 and dependent claims 10-13, the rejection of record indicates that the specification does not provide adequate written description of the claimed genus of "a ligand of a class III tyrosine kinase receptor". Applicant made no amendment or argument in response to this aspect of the rejection.
9. The remaining claims have been amended to recite, "or functional equivalents thereof capable of inhibiting differentiation of the stem cell." Applicant argues that one of ordinary skill in the art, based on the present disclosure, would be enabled to conduct routine tests to determine any potential functional equivalent which is capable of inhibiting stem cells, thereby providing clear metes and bounds of the claims. This is not persuasive because the claims still encompass a genus of molecules defined only by function with no structural limitations. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 102

10. Claims 1,8,9, 13, 14, 41, 63, 66, 69, and 70 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lindquist *et al.*, US Patent Publication No. 20040014662, filed 05/08/2003, with priority to US Provisional Patent application no. 60379114, filed 05/08/2002.

Applicant's arguments filed 04/20/2006 have been fully considered but they are not persuasive. Applicants argue that the limitation of the claimed methods to human stem cells renders the amended claims novel and non-obvious over the prior art of record. However, contrary to applicant's assertion, the Lindquist *et al.* publication does teach human cells at least at [0020, 0026, 0040, 0045, 0156] and claims 34, 39, and 51. Therefore the instant claims are anticipated by Lindquist *et al.* for reasons of record.

Conclusion

11. No claims are allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).
- Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG

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30 June 2006


DAVID S. ROMEO
PRIMARY EXAMINER